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Test and trace strategy has overlooked importance of clinical input, clinical oversight and integration

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Introduction

From 18th May in the UK patients, health and social care staff, and the public could arrange their own COVID 19 tests directly through government phone line or website in the absence of proper clinical input and oversight. This is despite the Royal College of Pathologists highlighting how problems with testing arise because of lack of clinical input, and emphasising how people being tested need to be informed about why they are being tested and the meaning of their results (1). In late summer 2020, multiple media outlets reported demand for tests (predominantly in England) as exceeding the capacity of the system, leaving many unable to access testing. However this is not the only concern regarding the current UK testing system. These relate to contractual arrangements, lack of clinical integration, and use of results. A new strategy is required, with clinical input, clinical oversight and integration into local primary care and public health systems.

Testing for covid-19

There are currently two main types of testing; for acute infection (presence of virus, via throat swab) and past infection (antibody). Testing for acute infection is used to support clinical diagnosis and clinical management of suspected cases; to inform contact tracing and case finding; to monitor and support outbreak control including testing of asymptomatic people in high risk settings, for example prisons, schools, care homes and hospitals. Testing for antibodies indicates past infection and is currently used for research and surveillance purposes. However both have significant caveats. The PCR test is not a test of infectiousness (2). A positive result detects viral RNA fragment in the sample but does not distinguish between those who have the virus and are infectious, and symptomless people who may or may not be infectious. The accuracy of testing in a real life population is unknown, but false negatives of up to 29% are reported (3). Because of this, clinical input is required to interpret, risk manage, and manage the results. This is essential to avoid false reassurance, leading to symptomatic people stopping isolation on the basis of a false negative test, risking spreading infection. Without clinical input, a risk based, clinically judged approach to the use of a negative result is lacking. Moreover, there is no reference to potential false negatives in NHS website advice, which currently reads: 'a negative result means the test did not find coronavirus' (4). There are still significant unknowns in regard to the real-life false negative rate in the community (5) The antibody test must also be carefully interpreted. A positive antibody test finds antibodies, but evidence as to whether this gives meaningful immunity or stops the spread of infection (6) is lacking. Additionally, there are ethical issues in the testing of asymptomatic people which require evidence-based information and consent. This, so far, appears to have been largely overlooked.

Testing in the UK was initially limited to hospital admissions and has been expanded across the population (Box 1). However, tests have been beset by problems over purpose, concerns about the quality, accuracy and relevance of published test data and reporting of test results (7,8).

Box 1 - Timeline of different routes to and eligibility for testing

- 12th March: PCR testing of symptomatic people in the community and contact tracing ends as strategy moves from 'contain' to 'delay' (9). Deputy CMO Jenny Harries told the health select committee on 5th May that this decision was related to capacity in the testing system (10). Testing now only performed for patients in hospital across the UK
 - 27th March: plans to start testing symptomatic NHS staff in England announced (11)
 - 2nd April: target set to do 100k tests/day in England (including antibody tests), prioritising hospital patients, NHS staff and then other key workers (12).
 - 23th April: key workers invited to apply for PCR tests through their employers, and from 24th April can self-refer (13).
 - 28th April: All patients over 70 screened in Scottish hospitals (14)
 - 28th April (England)(15) and 1st May (Scotland) (16): people over 65 and those who must leave home to work, as well as those they live with, are able to get tested if they have symptoms of the virus.
 - 18th May: Anyone in UK with symptoms able to apply for a test online or by telephone (17)
 - 27th May: Test and Trace launched across England (18)
 - 28th May: Test and Protect launched in Scotland (19)
 - 30th July: Plans set out to expand UK's testing capacity to 500,000 tests a day over next 6 months (20)
- Care homes**
- PCR Testing in care homes for outbreaks only (first 5 residents with symptoms are tested), until 15th April in England when all symptomatic residents were eligible for tests and those being discharged from hospital into care homes were required to have a test (21) (result did not have to be back before discharge (22)) Scotland followed on 21st April (23).
 - 28th April: testing offered for all care home residents and staff in England, whether they have symptoms or not (24)
 - 1st May: enhanced outbreak testing in Scottish care homes - whole home tested if there is a confirmed case and sampling of care home residents and staff where there are no cases (25)
 - 11th May: all staff and residents in elderly care homes in England to be offered tests by 6th June, on a repeating basis (26)
 - 18th May: routine testing of care home staff on a repeating basis, regardless of whether symptomatic, in Scotland. (27)
 - 8th June: all UK adult care homes to be offered whole home testing (28)
 - 3rd July: UK plans announced for all care home staff to be tested weekly, and residents monthly (29)

Testing is only of value when it is part of a complete system which is capable of reducing the burden of coronavirus.

Lack of clinical integration

One of the key failures in responding to the epidemic was the government's decision to take testing out of public health services and local authorities. Normally, testing is done via a health professional whose role is in clinical assessment, advice regarding testing, interpretation and then explanation of the results, together with undertaking statutory notification. A test is simply a diagnostic tool. Because the current PCR COVID test is not a test of infectiousness, it cannot distinguish between those who have the virus and capable of infecting others, and those who have remnants of the virus but are not infectious. Clinical interpretation is therefore important for advice and diagnosis. In setting up a parallel testing system in the private sector, local public

health departments and primary care were separated from the testing system. As a result the statutory notification system for reporting suspected cases was not followed. This resulted in poor community data which is likely to have delayed outbreak control.

An optimal system would ensure access to evidence-based advice and testing, reliable, rapid laboratory analysis, swift reporting of results, professionally guided interpretation of results in the context of clinical symptoms, and advice on the limitations of testing. This needs to be followed by contact tracing, isolation advice, and the material, medical and mental health support to do so.

Many GPs have complained of their inability to request covid-19 PCR swabs in practice, having to refer patients to centralised testing sites. It is important to note that the four nations have gone in different directions with regard to testing and integration with local public health teams. Results on tests, initially not delivered to GPs at all, now arrive without enough information for interpretation or for epidemiological purposes, lacking information on reason for testing, or risk factors.

The UK Government strategy for testing, published 2nd April, is to support the development of a UK diagnostics industry (pillar 5) by expanding commercial testing for PCR and antibody tests through pillars 2,3 and 4. These tests are delivered by Thermo Fisher Scientific, Amazon, Boots, Royal Mail and Randox, alongside the Wellcome Trust, Lighthouse labs and some universities (see appendix 1– for online version). However, these test results may not all have been notified by the laboratories (30), have not been integrated with primary care nor do they provide real time data to local authorities (31).

Patient and community outcomes

Positive results should be seamlessly co-ordinated by a public health response and clinical input as needed from primary care. However, in England public health directors have described how they have not been given enough real time patient information to enable contact tracing from pillar 2 test sites. The disease notification system in England was amended in 2010 requiring laboratories to notify PHE of test results but there is no longer a requirement to notify directors of public health and their proper officers – this means data has not been flowing locally (32). Reports from local public health departments indicated that, despite the central government saying they had all the information they needed for contact tracing, detailed 6/7 digit postcode level data was not provided, limiting the effectiveness of their response (33). Moreover, the contact tracing services in England comprise a parallel system of centralized, privatised call handling centres run by Serco and Sital while health protection teams operating out of PHE handle the complex cases from institutional settings eg care homes and workplaces. The performance measures for Serco, Capita and those employed by NHS professionals have not been published. However test and trace data in August highlighted how the call handlers were reaching only 61% of contacts, compared with over 95% for the public health teams (34). Less than a fifth of people intend or manage to follow test, trace and isolate advice, raising questions about how effective the current system for protecting individuals and the public is (35). In a localised outbreak in north England, centralised contact tracing reached only 50% of close contacts (36) but once given adequate information on people with positive test results, local public health teams set up their own contact tracing teams, with the local Director of Public Health tweeting on 8/8/20 that “we are now managing to contact 9/10 of the cases the national system could not contact.” (37). Mopping up the failures of the privatized system is expensive and diverts money from other local authority services. In England,

Serco and Sital's contracts, which were set to expire on August 23rd, have been extended by a projected £528 million (38) to over £700 million.

Despite the failings of this largely private, highly centralised NHS Test and Trace system, it has been reported that the government intends to scale up testing to deliver weekly tests for the whole population. Deloitte and a slew of commercial companies are being contracted to deliver them under Operation Moonshot, a plan to ramp up tests to 10 million a day, at a cost of 100 billion pounds – 70% of the annual NHS budget for England. Ten million tests a day will generate 10,000 people testing falsely positive a day and result in unnecessary isolation and hardship for them and their contacts. (2)

The way forward

Primary care services across the UK were excluded from management and care of covid patients at the start of the epidemic. They are currently dealing with radical changes to their way of working, implemented over a short period of time (39). As we move towards winter planning, a longer-term response is crucial and the reality of multimorbidity, the multiple symptoms of potential coronavirus, and the long term care of patients with protracted symptoms needs to be considered. This will require significant investment in primary care and local public health services and NHS labs. Diverting the highly resourced funding from the ineffective and privatised test and trace service to local services would avoid fragmentation created by private companies and restore and rebuild much needed capacity. McKinsey has been paid £560,000 by the government to conduct a review of the inefficient test and trace system (40); however, without local public health and general practice expertise, it will continue to be ineffective. While the UK- wide testing programme is privatised and England's tracing system is run by Serco and Sital, Wales and Scotland have opted for locally run contact tracing systems. We consider that equivalent funding managed by local public health and primary care would be, by virtue of expertise and local knowledge, be better able to expand services according to needs in response to the pandemic. Clinical, rather than corporate leadership would ensure that the complexity of testing was acknowledged and accounted for, while drawing on the integrated nature of local public health departments. We call on the Westminster government to end privatisation of testing and to reinstate and invest in NHS primary care, public health, and NHS laboratory services, and redirect the resources from the current private testing programmes back into the local primary care, local NHS labs and local public health sector, directed by clinically-led need and with clinical oversight.

Competing Interests

Our DOI is at whopaysthisdoctor.org and all authors are strong supporters of a publicly funded comprehensive NHS

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Guarantor

AMP

Contributorship

AMP, LHE and MM contributed equally to all drafts of the paper.

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